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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,931	10/02/2003	Philip Harris	31611-11	9591
24256	7590	06/23/2006		
DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			EXAMINER	
			DANG, IAN D	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/677,931	HARRIS, PHILIP	
	Examiner Ian Dang	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 October 2003.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-9 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

Claims 1-9 are under consideration by the examiner.

### *Specification*

The use of the trademark SOMAVERT has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Rejections - 35 USC § 112 (written description)*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.

The factors to be considered include disclosure of complete or partial structure/function correlation, and other identifying characteristics.

The claims are drawn to a method of treatment for headaches with any growth hormone receptor antagonists. While the class of compounds classified as Cox-2 inhibitors are known in the art, such is not the case for the broad genus of growth hormone receptor antagonists. In analyzing whether the written description for the growth hormone receptor antagonist is met for genus claims, it is first determined whether a representative number of species have been described by the complete structure. Applicant's specification provides only a single example of a trial with patients with acromegaly treated with the growth hormone receptor antagonist pegvisomant, but does not provide sufficient relevant identifying characteristics for other growth hormone receptor antagonists. In this case, the specification discloses the growth hormone variant, pegvisomant, as the only growth hormone receptor antagonist without identifying any specific structures for this or any other antagonists.

Next it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics, special features and functional attributes to place applicant in possession of the claimed genus. Applicant's disclosure fails to do so. For instance, an antibody or small molecule might also function as a growth hormone receptor antagonist; however, no such antagonists are set forth in applicant's disclosure. Although Applicants has identified the functional attribute for the growth hormone receptor antagonist, further structural studies are necessary to determine the physical and chemical attributes important to antagonize the growth hormone receptor and identify a sufficient number of species to place applicant in possession of the broad genus of growth hormone receptor antagonists.

Accordingly, in the absence of sufficient recitation of distinguishing structural/physical and identifying characteristics, the specification does not provide adequate written description of the claimed genus.

***Claim Rejections - 35 USC § 112 (enablement)***

Claim 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating headaches in patients with acromegaly with the growth hormone receptor antagonist pegvisomant with one of the COX-2 inhibitors selected from celecoxib, valdecoxib, parecoxib, rofecoxib, and etoricoxib, does not reasonably provide enablement for any other growth hormone receptor antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include: (1) Nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the breadth of the claims, (7) the quantity of experimentation needed, (8) relative skill of those in the art.

**Nature of the invention and breadth of the claims**

The claims are drawn to a method of treatment for treating headaches in patients with acromegaly with a COX-2 inhibitor and a growth hormone receptor antagonist. The invention is broad because the recitation of claim 1 encompasses administration of any growth hormone receptor inhibitors with any COX-2 inhibitors.

The state of the prior art

The art teaches that patients with acromegaly have abnormal elevated growth hormone levels circulating in their bloodstream. Trainer et al. teaches a method of treatment for patients with acromegaly by administering the growth hormone receptor antagonist pegvisomant (The New England Journal of Medicine, 2000, Volume 342 Number 16, page 1171-1177). Results from the study disclose that pegvisomant is an effective treatment for relieving the clinical symptoms in patients with acromegaly. However, the art is silent as to the identity and therapeutic efficacy of any other growth hormone receptor antagonists.

The amount of direction or guidance present

Applicant's disclosure is limited to the administration of a single growth hormone receptor antagonist, pegvisomant, in conjunction with a Cox-2 inhibitor. There is a single working example directed to administration of the growth hormone receptor antagonist pegvisomant in conjunction with the Cox-2 inhibitor celecoxib. There is no guidance in applicant's disclosure as to what other inhibitors might be administered in conjunction with a Cox-2 inhibitor. There are no working examples drawn to the administration of any additional inhibitors in conjunction with a Cox-2 inhibitor.

The quantity of experimentation needed

Because the claims are broadly drawn to administration of any growth hormone receptor antagonist in combination with a Cox-2 inhibitor for treatment of patients with acromegaly, because the art is silent as to therapeutic administration of antagonists other than pegvisomant, and because Applicant's disclosure does not contain sufficient teachings to overcome the

unpredictability taught in the art, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9 Applicants recite a method for the preparation of a medicament but the claim does not teach any active steps. The claim is incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under U.S.C. 103(a) as being obvious over Trainer et al. (2000) in view of Harrison et al. (1994) and Aukerman et al. (2002).

Trainer et al. teaches a method for the treatment of patients with acromegaly with the growth hormone receptor antagonist pegvisomant. The method of treatment improves significantly the clinical symptoms of patients with acromegaly. Trainer et al. does not teach the use of a COX-2 inhibitor for treating headaches in patients with acromegaly.

Harrison et al. recites that patients with acromegaly have several neurological symptoms including headaches.

Aukerman et al. (2002) teaches that patients with headaches can be treated successfully with numerous COX-2 inhibitors consisting of several non-steroidal anti-inflammatory drugs. Cox-2 inhibitors have been shown to be an effective treatment for headaches.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to administer pegvisomant to patients with acromegaly as taught by Trainer et al. in combination with a COX-2 inhibitor because Harrison et al. teaches that those patients experience headaches and Aukerman et al. teaches the administration of Cox-2 inhibitors to treat headaches. Accordingly, the invention taken as a whole is *prima facie* obvious.

### **Conclusion**

No claims are allowed

**Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ian Dang  
Patent Examiner  
Art Unit 1647  
April 20, 2006

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